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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/540,343 | 10/06/1995 | DENNIS E. HALLAHAN | ARCD:194 | 8900 |

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09/05/2002

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/540,343

Applicant(s)

HALLAHAN ET AL.

Examiner

Scott Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,10,11,13,15,18-27 and 35-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,10,11,13,15,18-27 and 35-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed 6/11/02 has been entered. Claims 38 and 55 have been amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102 & 103

Claims 8, 10, 11, 13, 15, 18-27 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by Martuza et al., US 5,585,096, filed 7/94 - hereafter Martuza A.

Claims 8, 10, 11, 13, 15, 18-27 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by Martuza et al., US 5,728,379 (filed 6/1995 and claiming priority to US 5,585,096, filed 7/94) - hereafter Martuza B.

Claims 35-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick, US 5,846,945 (filed 6/1995, claiming priority to applications filed 2/1994 and 2/1993) in view of a) either Martuza A or Martuza B, or b) Frisch, US 5,776,743 (filed 9/1994); or c) Frisch and either Martuza A or Martuza B.

Response to Arguments

Applicant's arguments filed 6/11/02 have been fully considered but they are not persuasive. Applicant argues that neither Martuza A nor Martuza B enables the combination of

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radiotherapy and oncolytic herpes viral therapy, because of lack of detailed guidance on conducting radiotherapy and working examples demonstrating the combination therapy. In response, Applicant does not dispute that the patents enable the oncolytic therapy disclosed therein (and claimed in Martuza B). The issue then is whether the radiation therapy is enabled. However, at the time the Martuza applications were filed, the use of radiotherapy in the treatment of cancer had been long established, as acknowledged in the instant specification at page 21. Indeed, the instant specification relies on the prior art for teaching radiation therapy here. As Applicant is well aware, a specification need not include that which is well known in the art, and preferably omits it, nor are working examples required to provide an enabling disclosure. Applicant has provided no evidence that one of skill in the art would require guidance to carry out radiation therapy in conjunction with the oncolytic viral therapy, nor that it would require undue experimentation. The burden is on Applicant to provide "facts" that a prior art invention is inoperable or not enabled. See MPEP 2121.

With respect to McCormick in combination with either of the Martuza patents and/or Frisch, McCormick taught the oncolytic adenoviral therapy could "be combined with other antineoplastic protocols", specifically naming chemotherapy as an example. The Martuza patents clearly show that radiotherapy was a known antineoplastic protocol that one of skill would have been aware of that could be used in combination with oncolytic viral therapy when McCormick regarding the teachings of McCormick to combine the adenoviral therapy with "other antineoplastic protocols". Applicant does not dispute that the adenoviral therapy is enabled.

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With respect to Frisch, Applicant is respectfully referred to col. 4, lines 13-15 where Frisch explicitly teaches using an adenovirus to introduce E1A into cells. Frisch is relied upon to show that one of skill in the art was aware that the adenoviral E1A protein sensitized tumor cells to radiation, providing motivation to use radiation therapy as one of the "antineoplastic protocols" referred to by McCormick. It is unclear what point Applicant is attempting to make in pointing out that the claims in Frisch are limited to *in vitro* delivery. Applicant has provided no evidence to support the speculations presented in the response as to why the Frisch claims were limited to tumor cells *in vitro*. The rejection is based on the disclosure of Frisch as a whole, not just the claims (which are sufficiently broad to embrace an Ad5 for delivery of E1A).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

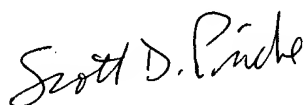
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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Technology Center 1600
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